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Automatic Vacuum Switch (AVS)

Instructions for Use and Installation

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Representation

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	**Conformité Européenne (CE) Mark**	Compliance with conformity assessment on quality management system and technical documentation per Regulations (EU) 2017/745 for Medical Device, Annex IX Chapters i & III
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READ MANUAL COMPLETELY BEFORE OPERATING THIS DEVICE

This document contains warnings, cautions, instructions for use, and maintenance information that the user must completely comprehend before using this device. Failure to properly operate and maintain this device may result in patient and/or user harm and/or damage to equipment.

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WARNING: This product can expose you to chemicals, including lead, which are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

CAUTION: Federal law restricts this device to sale by or on the order of a physician or dentist.

Visit our website: https://www.porterinstrument.com/dental/porter-automatic-vacuum-switch for additional information. To download Instructions for Use: visit https://www.porterinstrument.com/dental-support Choose “Automatic Vacuum Switch” from the dropdown within the “Product Download” section.

1. Device Information

1.1. Intended Use

The AVS is intended to control the vacuum flowrate and scavenging of waste analgesic gas.

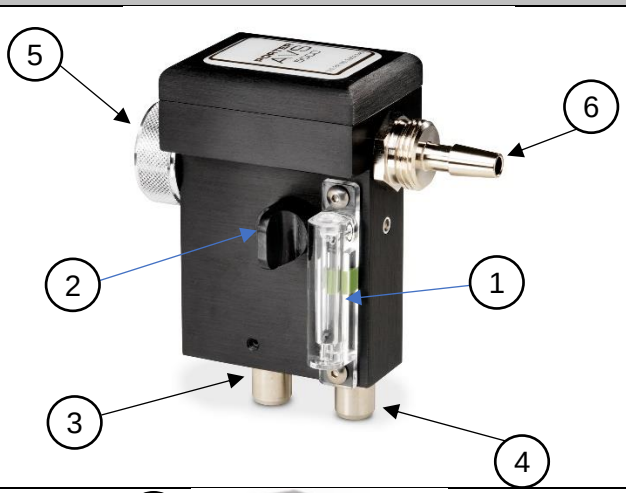
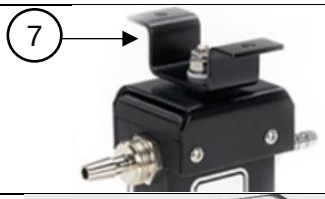
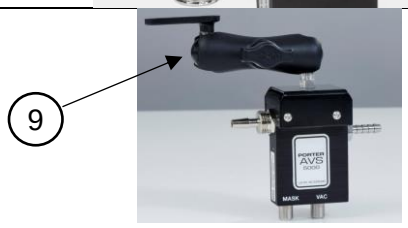
1.2. Models

The AVS is available in 5 models. The vacuum controllers are available with different mounting configurations. Through this document, the AVS-5000 model is pictured. All instructions and information are the same for all models unless specified otherwise.

Model Number	Model Description
AVS-5000*	Automatic Vacuum Switch
AVS-5000QD*	Automatic Vacuum Switch, Quick Disconnect
AVS-5000S*	Automatic Vacuum Switch, Swivel Mount
AVS-5000B*	Automatic Vacuum Switch, Bracket Mount
AVS-5000C*	Automatic Vacuum Switch, Ball Mount

*Denoted as CE Certified and available on European Market. Other models may be available on other international markets.

1.3. User Interface

#	Description	Image
1	Sight glass	
2	Control knob	
3	Vacuum port	
4	Mask port	
5	Flowmeter connection	
6	Fresh gas outlet	
7	Swivel Mount	
8	Quick Disconnect Mount	
9	Chair Mount	

1.4. General Description/Principles of Operation

The AVS is a mechanical/pneumatic vacuum controller that allows adjustment of the rate at which waste analgesic gas is scavenged away from the patient. The AVS features an adjustable switch and a ball float sight glass to monitor the amount of vacuum pressure applied to the exhalation line of the main device. It is designed with an automatic interlock mechanism that automatically turns on the vacuum source when the device system is active. The AVS also features automatic detection of vacuum pressure that prevents the administration of mixed gas to the patient when the gas disposal system is not active.

The AVS connects the exhalation line of the patient's breathing circuit to vacuum tubing from the vacuum source controls the vacuum flowrate. The device also connects the inhalation line of the patient's breathing circuit with the conscious sedation flowmeter and prevents the flow of gas without vacuum pressure being applied. The rate at which the gas is removed is specified by the AVS, which uses an adjustable orifice to limit the amount of vacuum applied to the exhalation line of the breathing circuit. Vacuum pressure applied within the device allows for mechanisms to open the gas pathway for gas to flow through the device between the flowmeter and breathing circuit. The gas exits the AVS through the vacuum tubing connected to the back of the device and is removed from the healthcare facility via the vacuum source. The device features vacuum flowrate control using an adjustment knob and flow indication displayed using a glass tube.

The AVS Circuit is equipped with safety features described in Section 1.7.

1.5. Use of the Device

The AVS is intended to be used by medical professionals trained in the use and administration of nitrous oxide (N_2O) and oxygen (O_2) gases. The device is designed for use in a gas delivery and scavenging system for pain management and / or minimal conscious sedation, which is ideal for short, minimally invasive procedures to alleviate patient anxiety or minor pain and discomfort. It is the responsibility of the medical professional to consider the side effects, contraindications, and risks associated with administration of N_2O and use of conscious sedation. The AVS is not used as part of, or in conjunction with, a general anesthesia administration system. This device should only be used to scavenge N_2O and O_2 medical gases.

WARNING: Do not use this device for the administration of general anesthesia or as part of, or in conjunction with, a general anesthesia administration system.

NOTE: If a serious incident (death or any intervention) has occurred while the device was in use, it should be reported to the manufacturer immediately and the Competent Authority of the member state in which the serious incident occurred.

1.6. Patient Population

The patient population includes conscious, spontaneously breathing, awake, alert, and cooperative patients.

Patients are selected by a medical professional trained in the use and administration of nitrous oxide and oxygen gases. The medical professional must consider patients who are able to receive the gas mixture based on the risks associated with conscious sedation.

1.7. Warnings & Cautions

Warnings and cautions are listed where relevant to a certain section of this manual. A **WARNING** is an instruction, procedure, or explanation of hazards that may result in personal injury or death. A **CAUTION** is an instruction, procedure, or explanation of hazards that may result in damage to a product, equipment, or the environment.

WARNINGS and **CAUTIONS** are presented throughout the document along with this symbol to alert the reader of their presence.

1.8. Safety Features

Automated Vacuum Activation

The AVS is designed with an automated vacuum activation mechanism to ensure that vacuum flow will begin once fresh gas begins to flow.

WARNING: The AVS is used with the delivery of Oxygen (O_2). Therefore, when this device is used in conjunction with energy producing devices (such as lasers, radio frequency sources, or other heat sources), the user must adhere to the instructions for use of those devices to avoid ignition of combustible materials.

WARNING: The Automatic Vacuum Switch is not intended or expected to be used during an MR exam and has not been evaluated for safety and compatibility in the MR environment. The safety of the Automatic Vacuum Switch in the MR environment is unknown, but due to the presence of materials in the device's accessories that may be ferromagnetic, the Automatic Vacuum Switch should be considered "MR Unsafe" and should be kept outside of any MRI scanner rooms.

1.9. Safe Combination of devices

The AVS is designed to be used within a nitrous oxide/oxygen conscious sedation delivery and scavenging system to deliver an accurate mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device system is also used to remove exhaled waste analgesic gas through a vacuum control system. The system is comprised of a series of devices and accessories, which includes a conscious sedation flowmeter, bag tee with breathing bag (if applicable), breathing circuit with nasal hood, vacuum controller, mounting stand, and gas supply hoses.

To ensure safe combination of device, user should follow the installation instructions in **Section 2** below and ensure all connections are secure and tight.

1.10. Delivery Protocols

It is the responsibility of the medical establishment and the healthcare professional to develop specific delivery protocols for administration of N_2O using the AVS. Specific delivery protocols for adult and pediatric patients should be developed.

The AVS is considered transient (less than 60 minutes) in terms of continuous use when providing analgesia (minimal sedation). Procedures that occur intermittently over the course of many hours may also be considered transient. The upper limit of use duration is at the discretion of the medical professional.

1.11. Specifications

Dimensions (in) (L x W x H)

See Section 5 Dimensions and Weights

Weight (lbs)

See Section 5 Dimensions and Weights

Connection Fittings

Mixed Gas Inlet (ID):
AVS-5000: ¾-16 UNF 2B F Thread
AVS-5000S: ¼ bard
AVS-5000QD: ¾-16 UNF 2B F Thread
AVS-5000C: ¼ bard
AVS-5000B: ¼ bard

Mixed Gas Inlet (ID):
AVS-5000: ¾-16 UNF 2A M Thread/0.255 barb
AVS-5000S: ¾-16 UNF 2A M Thread/0.255 barb
AVS-5000QD: ¾-16 UNF 2A M Thread
AVS-5000C: ¾-16 UNF 2A M Thread/0.255 barb
AVS-5000B: ¾-16 UNF 2A M Thread/0.255 barb

Vacuum Outlet (ID): 0.36 inches
Vacuum Supply: 3/8 in barb

Environmental

Temperature
Storage/Transport: -40°F - 140°F (-40°C - 60°C)
Operational: 40°F -100°F (4°C - 38°C)

Relative Humidity
Storage/Transport: ambient
Operational: ambient, non-condensing

Gas Supply Pressure

N_2O: 50-55 psi (344.7 – 379.2 kPa)
O_2: 50-55 psi (344.7 – 379.2 kPa)

Recommended Vacuum Source Characteristics

Source Pressure Range: 10 to 21 inHg (33.8 to 71.1 kPa)
Flow rate: 50 L/min minimum

Atmospheric Pressure

1 atm ±0.2 atm (101 kPa ±20 kPa)

Operational Characteristics

Operating Pressure Range: 3 to 8 inHg (10.2 to 27.1 kPa)

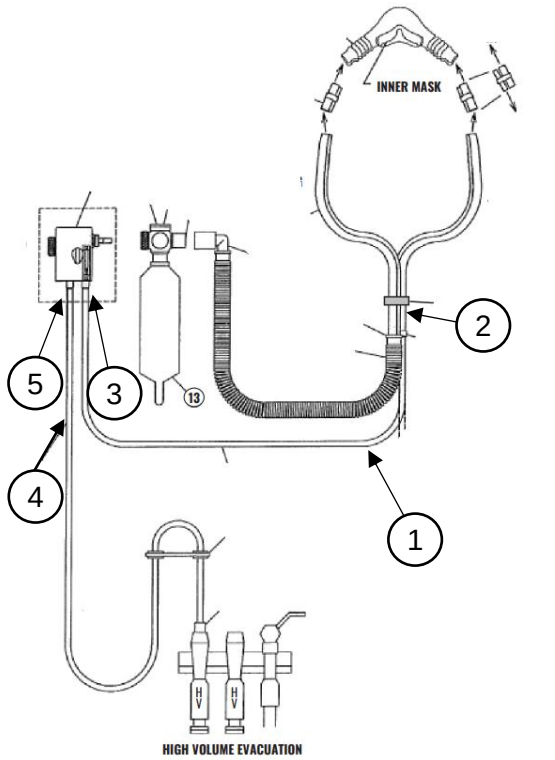
2. Installation Instructions

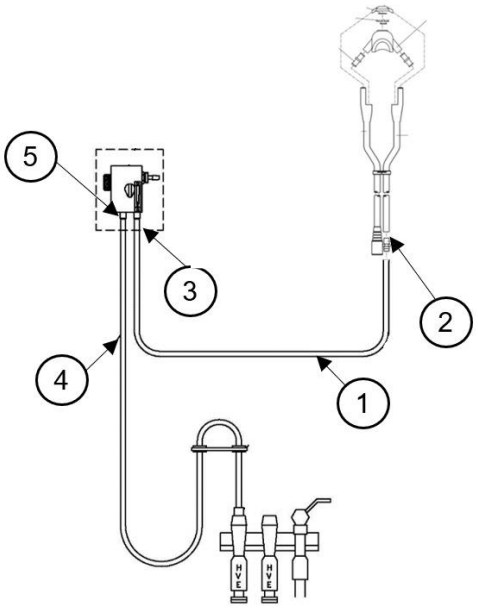
2.1. Installing the Automatic Vacuum Switch

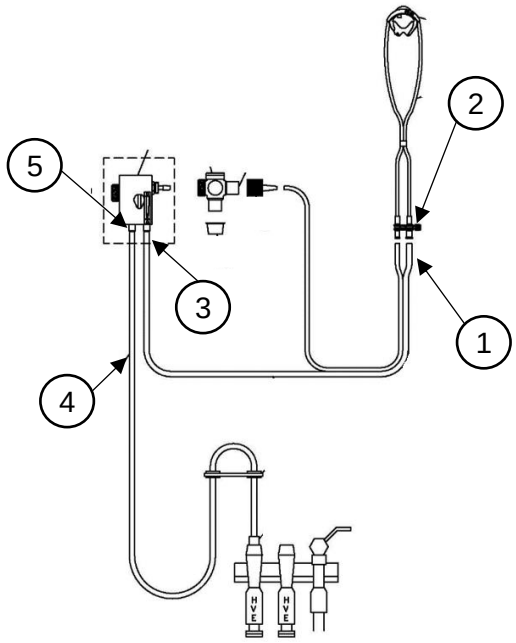
WARNING: For centrally piped facilities, properly connected gas pipelines are essential to patient safety. The ultimate responsibility of assuring that lines are not crossed rests with the user. Per NFPA 99, the certified medical gas plumber, and verifier, should provide written documentation that all gas pipelines are connected properly and that all use points of the system have been tested prior to use. It is important that the user verify by their own test that all gas pipelines are connected properly prior to using the system.

Note: If an Automatic Vacuum Switch is to be used with a nitrous oxide and oxygen conscious sedation delivery system, the AVS should be installed before mounting the device.

Note: The Automatic Vacuum Switch is compatible with the Porter, Matrx, and Silhouette breathing circuits.

Automatic Vacuum Switch with Porter Breathing Circuit		
1	Attach the **Vacuum Hose** (1) to the smaller diameter of the **Porter Breathing Circuit** (2).	
2	Attach the other end the **Vacuum Hose** to the **MASK port** (labeled on body) of the **AVS** (3)	
3	Attach a second **Vacuum Hose** (4) to the **VAC port** (labeled on body) of the **AVS** (5)	
4	Attach other end of the **Vacuum Hose** (4) to the vacuum source. **Note:** Additional parts may be needed in order to connect to a vacuum source.	

Automatic Vacuum Switch with Matrx Breathing Circuit		
1	Attach the **Vacuum Hose** (1) to the smaller diameter of the vacuum tubing of the **Matrx Breathing Circuit/shut off valve** (2)	
2	Attach the other end the **Vacuum Hose** (1) to the **MASK port** (labeled on body) of the **AVS** (3)	
3	Attach a second **vacuum hose** (4) to the **VAC port** (labeled on body) of the **AVS** (5)	
4	Attach the other end of the **vacuum hose** (4) to the vacuum source. **Note:** Additional parts may be needed in order to connect to a vacuum source.	

Automatic Vacuum Switch with Silhouette Breathing Circuit		
1	Attach one end of the larger diameter **Fresh Gas and Vacuum Hose** (1) to the larger diameter of the H-Union of the **Silhouette Disposable Circuit** (2).	
2	Attach the other end the larger diameter **Fresh Gas and Vacuum Hose** to the **MASK port** (labeled on body) of the **AVS** (3)	
3	Attach a second **vacuum hose** (4) to the **VAC port** (labeled on body) of the **AVS** (5)	
4	Attach the other end of the **vacuum hose** (4) to the vacuum source. **Note:** Additional parts may be needed in order to connect to a vacuum source.	

3.Instructions for Use

3.1. Setup and Pre-Use Checks

WARNING: The user should observe the patient to prevent over sedation in the event of an O_2 failsafe malfunction or a crossed lines situation. If a patient becomes overly sedated when being delivered 100% O_2, immediately remove the mask and encourage mouth breathing. This is an indication of a failsafe malfunction or crossed lines. In this case, only deliver pure O_2 from an independent source.

WARNING: Always use clean, dry, medical grade gases and never oil or grease any part of the device.

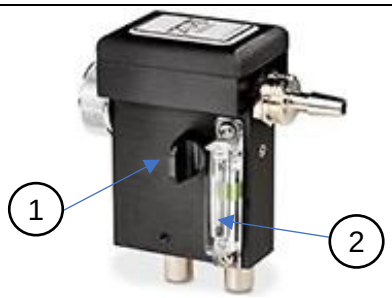
1	Ensure the Automatic Vacuum Switch is adequately mounted in conjunction with the conscious sedation system.
2	Ensure the necessary pre-checks have been performed, before using the Automatic Vacuum Switch. The pre-check instructions are described in **Section 4.1 Pre-Checks**.
3	Ensure all connections are tight and secure.

3.2. Operating Instructions

WARNING: Workers exposed to excessive N_2O may suffer harmful effects. The healthcare professional is responsible for employing proper techniques, such as scavenging, room ventilation, system maintenance, and patient compliance to reduce exposure. (ACGIH recommends a Threshold Limit Value of 50 parts per million over an 8-hour time-weighted average).

CAUTION: It is best practice upon completion of the procedure to close the cylinders (if portable gas supply) or disconnect from wall outlets (if central gas supply). Failure to do so may result in gas depletion should there be a leak.

CAUTION: Do not process any liquids or debris through the AVS. The AVS is designed to regulate vacuum flow level for scavenging N_2O/O_2 gas only.

1	To adjust vacuum flow, the applicable Breathing Circuit must be fully installed	
2	The AVS will automatically open upon the delivery of 1.5 to 3.5 L/min of gas flow. Start with the **vacuum control knob** in horizontal position.	
3	Adjust vacuum flow by using the **vacuum control knob** (1) and **sight glass** (2) to monitor vacuum flow. Set the **vacuum control knob** to the desired level of vacuum flow. The Highest vacuum flow is horizontal position. The lowest vacuum flow is vertical position. **Note:** The recommended vacuum flow is when the ball float is within the green band on the **sight glass.**	

4. Maintenance

The Automatic Vacuum Switch has an expected lifetime of 10 years and requires proper maintenance, pre-checks, and servicing according to the following table. Once the device reaches an age of 10 years, a failed pre-check will indicate that the device has reached the end of its useful life.

Check	Frequency
Inspect AVS, hoses, fittings, and connections for damage, wear, and leaks	Before every Use
AVS Check	Daily

WARNING: Proper inspection and maintenance of this device is essential to prevent gas leaks. All hoses, fittings, and connections should be inspected regularly, and all leaks should be repaired immediately.

WARNING: Do not change the connection fitting type or diameter of the supply hoses. The Diameter Indexed Safety System (DISS) is designed to prevent misconnection of N_2O and O_2 supply lines.

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: Do not use or replace any components or accessories, except those specified in these instructions for use and installation guide.

4.1. Pre-Check

To perform the following tests, a compatible breathing circuit and proper connection to the vacuum supply are required.

WARNING: If precheck test cannot be executed successfully, do not use this device and contact distributor.

AVS Check

1	Ensure there is no vacuum hose connected from the mask port on the AVS
2	Turn the Consious Sedation Flowmeter On
3	Start a procedure, ensuring only O_2 gas is flowing
4	Create a seal by placing your hand over the mask port on the AVS, you should feel suction on your hand
5	If you feel no suction on your hand, contact your authorized distributor for service and troubleshooting

Field Performance Check of Adjustment of Vacuum Flow Using the AVS

1	**Set a high flow:** After assembly of AVS and Scavenging System to the Flowmeter, set flowmeter to flow 8 L/min of 100% Oxygen to fully open AVS vacuum interlock.
2	**Set vacuum level (green bar or higher):** Turn vacuum control knob to set vacuum flow, as indicated by the vacuum indicator, in the desired area. **NOTE:** Porter recommends that effective scavenging can be achieved with the ball float in the green bar area of the acrylic sight glass, however NIOSH publications conclude that higher vacuum flows of up to 45 L/min are most effective. To meet the NIOSH recommendation of 45 L/min, adjust the ball above the green bar area.
3	**Close the flowmeter flow to zero.** The ball float will drop to the bottom of the sight glass.
4	**Check at low flow:** Open the flowmeter, again with 100% Oxygen, slowly to 3.5 L/min. Observe that the AVS vacuum flow indicator reaches the same level as in the setting of Step 2.
5	If low flow check does not show high enough vacuum flow, repeat Steps 1 - 4, and adjust vacuum control knob to a higher vacuum flow setting. Effective scavenging is achieved if vacuum flow can be verified to be within the green bar area of the acrylic sight glass. However, if the check of Step 4 fails, it may be an indication that the AVS requires maintenance. Contact your authorized distributor.

4.2. Cleaning the Device

The Automatic Vacuum Switch must be cleaned between each use in order to prevent the spread of infections. Cleaning of the device should be conducted with Super Sani-Cloth™ Germicidal or similar wipes.

WARNING: The following warning applies to the device and any device's components and accessories:

- Do not spray directly with disinfecting chemicals.
- Do not immerse in water, sanitizer, cleaning solution, or any other liquid.
- Do not sanitize or wipe the inside of the fittings, gas supply hoses, or connection ports.
- Always ensure the device and device's components and accessories are completely dry before use.

WARNING: Do not use Isopropyl Alcohol; use of Isopropyl Alcohol to clean or disinfect may damage device.

1	Disconnect and dispose of the single use breathing circuit and single use mask/mouthpiece (if attached). The vacuum hosing may be disconnected and wiped down.
2	Using a Super Sani-Cloth™ Germicidal wipe, thoroughly wipe down the outer case, vacuum flow knob, and back of the device until all visible dirt and soil is removed. Take extra care to wipe the outside of the connection port area and vacuum control knob area as these are the most handled areas of the device. A soft bristled brush may be used to loosen any soil that is difficult to remove.
3	Perform the setup and pre-use checks as specified in **Section 3.1 and 4.1**.

4.3. Disposal

It is best practice to inquire with local authorities for proper disposal guidelines, if applicable.

5. Dimensions and Weights

Dimensions (L x W x H)	Weight
AVS-5000 1.77 in x 4.05 in x 3.95 in 4.495 cm x 10.29 cm x 10.3 cm	**AVS-5000** 1.05 lbs (0.476 kg)
AVS-5000S 1.95 in x 4.658 in x 4.927 in 4.953 cm x 11.83 cm x 12.51 cm	**AVS-5000S** 1.15 lbs (0.522 kg)
AVS-5000QD 1.77 in x 3.31 in x 3.95 in 4.495 cm x 8.407 cm x 10.3 cm	**AVS-5000QD** 1 lbs (0.454 kg)
AVS-5000C 1.95 in x 4.658 in x 5.9 in 4.953 cm x 11.83 cm x 14.986 cm	**AVS-5000C** 1.2 lbs (0.544 kg)
AVS-5000B 1.95 in x 4.658 in x 4.66 in 4.953 cm x 11.83 cm x 11.836	**AVS-5000B** 1.1 lbs (0.50 kg)

6. Symbols Glossary

The following symbols are used throughout this document, as well as on device labels and packaging.

Symbol	Title of Symbol	Description of Symbol
	**Manufacturer Information**	Indicates the medical device manufacturer and is accompanied by the name and address of the manufacturer.

Symbol	Title of Symbol	Description of Symbol
	**Date of manufacture**	Indicates the date when the device was manufactured. This symbol is accompanied by four digits for the year the device was manufactured.
	**Country of manufacture**	Indicates the country where the device was manufactured.
	**Catalogue Number**	Indicates the manufacturer's catalogue number of the device and is used for identification of the device.
	**Serial Number**	Indicates the manufacturer's serial number of the device and is used for identification of the specific device.
	**Unique device identifier**	Indicates a carrier that contains unique device identifier information
	**Prescription device**	Indicates that federal law restricts this device to sale by or on the order of a physician or dentist.
	**Medical Device**	Indicates the item is a medical device
	**Consult Instructions for Use**	Indicates the need for the user to consult the instructions for use
	**Caution**	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself.
	**Caution/Warning**	Indicates important cautionary or warning information to the user that is presented in the instructions for use that accompanies explanatory instructions to the user
	**Conformité Européenne (CE) Mark**	Indicates that the product may be traded freely in any part of the European Economic Area, regardless of its country of origin.

7. Warranty

CERTIFICATE OF WARRANTY

THIS WARRANTY IS GIVEN IN PLACE OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE.

Under no circumstances shall Parker Hannifin Corporation be liable for incidental or consequential damages as those terms are defined in the uniform commercial code.

Parker Hannifin Corporation, Porter Instrument warrants that each product or part shall be free from defects in workmanship and materials, under normal use and with appropriate maintenance, for one (1) year from the date of delivery to customer unless otherwise specified in writing. All rubber and plastic parts and accessories are warranted under the same conditions for a period of ninety (90) days from date of purchase.

No statement or claim about the product by any employee, agent, representative, or dealer of Parker Hannifin Corporation shall constitute a warranty by Parker Hannifin Corporation or give to rise to any liability or obligation of Parker Hannifin Corporation.

Parker Hannifin Corporation shall not be liable for any damage, injury or loss arising out of the use of the product, whether as a result of a defect in the product or otherwise, if, prior to such damage, injury or loss, the product was (1) damaged or misused; (2) repaired, altered or modified by persons other than Parker Hannifin Corporation; (3) not installed in strict compliance with applicable codes and ordinances; or (4) not installed by an authorized Parker Hannifin Corporation dealer. Parker Hannifin Corporation's obligation for breach of this warranty, or for negligence or otherwise, shall be strictly and exclusively limited to the repair or replacement of the product or part. This warranty shall be void on any product on which the serial number has been altered, defaced or removed.

ORDERS All orders are to be made through authorized Parker Hannifin Corporation distributors. All billing will be done through said distributors. Direct orders will be handled through the authorized local dealer as determined by Parker Hannifin Corporation.

RETURNS All returned merchandise will be handled through the local Parker Hannifin Corporation distributor. No returns will be accepted unless authorized in writing by Parker Hannifin Corporation and accompanied by the original shipping invoice. All returns are subject to restocking charge.

Policies subject to change without notice.

To register your product: www.porterinstrument.com/medical-support and click on Warranty Registration Form button.